

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION**

SANDRA RHODES,)
)
Plaintiff,)
)
v.) Cause No. 3:12-CV-841-JVB-CAN
)
NEW ENGLAND COMPOUNDING)
PHARMACY, INC. a/k/a NEW)
ENGLAND COMPOUNDING CENTER;)
AMERIDOSE, LLC; ALAUNUS)
PHARMACEUTICAL, LLC; BARRY)
CADDEN; LISA CADDEN;)
and GREGORY CONIGLIARO,)
)
Defendants.)

**MEMORANDUM IN SUPPORT OF ALAUNUS
PHARMACEUTICAL, LLC'S MOTION TO DISMISS**

Defendant, Alaunus Pharmaceutical LLC, by and through its counsel, hereby moves the Court to dismiss Plaintiff's Complaint, as to Alaunus, for failure to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6).

I. INTRODUCTION

This is a products liability action commenced by Plaintiff, Sandra Rhodes ("Rhodes"), against Defendants, New England Compounding Pharmacy, Inc. ("NECC"), Ameridose, LLC ("Ameridose"), Alaunus Pharmaceutical LLC ("Alaunus"), Gregory Conigliaro ("Conigliaro"), and Barry Cadden and Lisa Cadden (collectively the "Caddens"). Plaintiff's Complaint asserts various causes of action collectively against the Defendants arising out of alleged injuries suffered from an injection of a steroid compound that she suspects was contaminated with a fungal agent and that she believes was manufactured and/or distributed by the Defendants. *See Pl. Comp., ¶¶ 6, 7, and 9.* Plaintiff's Complaint asserts eight (8) causes of action: Count I –

Strict Liability; Count II – Negligence; Count III – Negligence *Per Se*; Count IV – Misrepresentation; Count V – Breach of Warranties; Count VI – Alter-Ego, Joint Venture Liability; Count VII – Officer and Director Liability; and, Count VIII – Punitive Damages. *Id.*, generally. The only count which lists Alaunus as a defendant is Count VI (Alter-Ego, Joint Venture Liability).

Plaintiff's Complaint should be dismissed for three (3) reasons. First, Counts I – V of the Complaint are subsumed and pre-empted by the Indiana Product Liability Act ("IPLA"). Second, Plaintiff has failed to plead sufficient facts to establish a viable claim for relief under the IPLA. Third, Plaintiff has failed to plead facts sufficient to give rise to a reasonable inference that Alaunus is liable for the misconduct alleged. Plaintiff has failed to plead facts sufficient to give rise to a reasonable inference that Alaunus manufactured or distributed any defective product into the stream of commerce; that Plaintiff suffered a legally compensable injury; that Plaintiff's alleged injuries were caused by the defective product; or that the products allegedly consumed by Plaintiff are traceable to Alaunus. Finally, and perhaps most importantly Plaintiff's Complaint also fails to plead any facts to support a theory of alter-ego or joint venture liability. For these reasons, Plaintiff's Complaint should be dismissed for failure to state a claim pursuant to Rule 12(b)(6).

II. FACTUAL ALLEGATIONS IN THE COMPLAINT

Plaintiff's Complaint asserts that NECC manufactures, compounds, distributes, and sells injectable steroid medications including Methylprednisolone Acetate Product ("MAP"), a prescription steroid medication which is compounded and provided in liquid form thereby requiring an injection for administration. *Pl. Comp.* at ¶¶ 2, 3, and 6. The Complaint asserts that NECC, by and through its officers Conigliaro and Caddens, marketed and sold MAP to various

medical providers including OSMC in Elkhart, Indiana. *Id.* at ¶ 5. The Complaint alleges that NECC manufactured numerous vials of MAP and distributed those vials to numerous medical providers in various states even though those vials were contaminated with fungus and they had “the propensity upon injection to cause fungal based meningitis and spinal cord and brain damage, including fatal disease complications and death.” *Id.* at ¶¶ 6 - 7. The Complaint asserts that NECC recalled its products. *Id.* at ¶ 10. The Complaint further asserts that the Plaintiff received “one or more of these products at OSMC and/or Outpatient Surgery Center” in Elkhart, Indiana on unspecified dates which were “manufactured, distributed, compounded, promoted, tested, marketed, and sold by the Defendant, NECC, Caddens, and Conigliaro.” *Id.* at ¶ 8. As a result of her purported receipt of the epidural steroid injection(s), Plaintiff claims that she “developed fungal-based meningitis which resulted in serious illness and injury.” *Id.* at ¶ 9.

Although the Plaintiff concludes that NECC, Caddens, and Conigliaro manufactured and sold the injectable steroid vials to OSMC and OSMC Outpatient Surgery Center (collectively “OSMC”), the Complaint does not allege or specify any facts that might identify the injectable steroid that was used by OSMC to treat the Plaintiff. The Complaint does not specify the name of the manufacturer listed on the labeling of the injectable steroid vial that was allegedly used to treat the Plaintiff. Nor does the Complaint provide other critical identifying details regarding the injectable steroid including the lot number, production date, size/volume, whether the product was brand-name or generic, or whether the product was preservative free or not. Plaintiff’s Complaint is devoid of any factual specifics that would sufficiently identify the product or put Alaunus on notice of a viable claim.

III. STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a motion to dismiss for failure to

state a claim may be granted if a plaintiff fails to plead any set of facts that would support a state of claim for relief. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955 (2007); *Holman v. Indiana*, 211 F.3d 399, 402 (7th Cir. 2000). In ruling on a motion to dismiss, this Court must accept as true all facts asserted in the Complaint and draw all reasonable inferences from them in plaintiff's favor. *Id.* However, to survive a motion to dismiss, plaintiff must allege "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Plaintiff's factual allegations are required to show that his claim relief is more than "speculative" or merely "conceivable;" his claim must be "plausible on its face." *Id.* at 570 (holding that "[b]ecause the plaintiffs here have not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed").

To have facial plausibility, the complaint must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937 (2009). The *Twombly-Iqbal* plausibility standard implicates a two-step analysis. *Iqbal*, 129 S.Ct. at 1950. First, the court must separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited). *Iqbal*, 129 S.Ct. at 1950, citing *Twombly*, 127 S.Ct. 1955. Second, the court must determine whether the well-pleaded, non-conclusory factual allegations give rise to a plausible inference that the defendant is liable for the misconduct alleged. *See Iqbal*, 129 S.Ct. at 1950, citing *Twombly*, 127 S.Ct. 1955. Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint should be dismissed because it has alleged—but it has not "shown"— "that the pleader is entitled to relief." *Iqbal*, 129 S.Ct. at 1950.

IV. ARGUMENT

A. Plaintiff's Complaint Asserts Only Conclusory Assertions against Alaunus Which Should be Disregarded by the Court.

On a motion to dismiss, "a plaintiff's obligation to provide the 'grounds' of [his] 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" *Twombly*, 127 S.Ct. at 1965. A court need not accept as true "legal conclusions or threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Brooks v. Ross*, 578 F. 3d 574, 581 (7th Cir. 2009) (citing *Iqbal*).¹ When a plaintiff alleges a fact "upon information and belief," the assertion signifies that the "allegations are based on secondhand information that [the asserting party] believes to be true." *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011) (quoting Black's Law Dictionary 783 (7th ed. 1999)); *Zuk v. E. Pa. Psychiatric Inst. of the Med. Coll. of Pa.*, 103 F.3d 294, 299 (3d Cir. 1996). In the absence of factual allegations of secondhand information that the plaintiff believes to be true which logically compels or supports an allegation that is made "upon information and belief," such an allegation is merely a conclusory assertion that should not be deemed to be true by the court on a motion to dismiss. See *Twombly*, 127 S.Ct. at 1962-1963, and 1970. "Conclusions" only become "facts" for pleading purposes when conclusions are logically compelled, or at least supported, by the stated facts, as well as the reasonable inferences drawn therefrom. *Iqbal*, 129 S.Ct. at 1950 (conclusions are not entitled to the assumption of truth where they are not supported by factual allegations); *Brooks*, 578 F. 3d at 581; *The Dartmouth Review v. Dartmouth*

¹ See also *Maldonado v. Fontanes*, 568 F.3d 263, 266 (1st Cir. 2009) (naked assertions devoid of further factual enhancement need not be accepted on a 12(b)(6) motion); *Barrington Cove Ltd. Partnership v. Rhode Island Housing and Mortg. Finance Corp.*, 246 F.3d 1 (1st Cir. 2001) (ruling that the court should not credit "conclusory assertions, subjective characterizations, or outright vituperation").

College, 889 F.2d 13, 16 (1st Cir. 1989) (same).

Here, the allegations in Plaintiff's Complaint regarding Alaunus are nothing more than a formulaic recitation of the elements of alter-ego² and joint venture liability.³ The only allegations in the Complaint which even mention Alaunus are contained in Count VI ("Alter-Ego, Joint Venture"). In regards to the alter-ego theory, the Complaint states that:

Alaunus was "organized and operated as the alter-ego of [NECC] for the benefit and advantage of the alter-egos, and at all times relevant thereto the alter-egos exercised dominion and control over [NECC], and said corporate defendants [NECC] and affiliated companies [Ameridose] and [Alaunus] have so intermingled their business affairs, each with the other, that all of said corporate entity defendants are the alter-egos of each other." *Id.* at ¶ 50.

...
"[NECC] and affiliated companies [Ameridose] and [Alaunus] were at all times operated jointly and all such businesses were, and are, operated as a joint venture and/or in concert with each other." *Id.* at ¶ 51.

...
"[NECC] and affiliated companies [Ameridose] and [Alaunus] are in substance the same, and that the Defendant corporations are but the alter egos of each other, acting solely as a device to cause harm or prejudice to the creditors of the corporations." *Id.* at ¶ 52.

...
"[NECC] and affiliated companies [Ameridose] and [Alaunus], Barry Cadden, Lisa Cadden, and Gregory Conigliaro have engaged in a joint venture in the marketing and distribution of the injectable steroid medications which are the subject of this litigation." *Id.* at ¶ 57.

There are no *factual allegations* whatsoever concerning Alaunus in the factual background section of the Complaint. *See Pl. Comp., ¶¶ 1 – 10. Counts I – V, VII and VIII of the Complaint*

² In determining whether a corporation is merely an alter-ego of another corporation, the courts consider whether (1) similar corporate names were used; (2) the corporations shared common principal corporate officers, directors, and employees; (3) the business purposes of the corporations were similar; (4) the corporations were located in the same offices and used the same telephone numbers and business cards; (5) there was intermingling of business transactions, functions, property, employees, funds, records, and corporate names in dealing with the public. *See Ziese & Sons Excavating, Inc. v. Boyer Constr. Corp.*, 965 N.E.2d 713, 719 (Ind. Ct. App. 2012).

³ A joint venture has been defined as an association of two or more persons formed to carry out a single business enterprise for profit. *Byrd v. E.B.B. Farms*, 796 N.E.2d 747, 753 (Ind.Ct.App. 2003). For a joint venture to exist, the parties must be bound by an express or implied contract providing for (1) a community of interests, and (2) joint or mutual control, that is, an equal right to direct and govern the undertaking, that binds the parties to such an agreement. *Id.* at 754. A joint venture is similar to a partnership except that a joint venture contemplates only a single transaction. *Id.* A joint venture agreement must also provide for the sharing of profits. *Id.*

do not even mention Alaunus. *Id.* at ¶¶ 11 – 47. Thus, there are no *factual allegations* in the Complaint which would remotely support the theory that Alaunus is merely an alter-ego of NECC or the theory that Alaunus and NECC engaged in a joint venture in the manufacture and sale of MAP.

Count VI of Plaintiffs' Complaint fails under *Twombly-Iqbal*, because it is merely a formulaic recitation of a cause of action and nothing more. *See Twombly*, 127 S. Ct. at 1966; *see also Resolution Trust Corp. v. Driscoll*, 985 F.2d 44, 48 (1st Cir. 1993) (affirming dismissal of claims against corporate defendant because naked assertion of alter ego liability was not supported by sufficient factual allegations). The allegations do not put Alaunus on notice of what exactly it might have done to be liable under an alter-ego or joint venture theory of liability. *See Brooks*, 578 F. 3d at 582 (refusing to accept as true allegations of malicious prosecution since they were merely a formulaic recitation of the cause of action and nothing more). On this basis alone, Count VI of Plaintiffs' Complaint against Alaunus should be dismissed.

B. Counts I – VI of Plaintiff's Complaint Are Subsumed by the IPLA and Must be Dismissed.

The Indiana Products Liability Act (“the IPLA”) governs *all* product liability actions brought by a user or consumer,⁴ against a manufacturer⁵ or seller,⁶ and for physical harm caused

⁴ The IPLA defines a user or consumer, in relevant part, as “a purchaser, or any individual who uses or consumes the product.” Ind. Code § 34-6-2-29.

⁵ A manufacturer is defined as “a person or an entity that designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer.” Ind. Code § 34-6-2-77. The definition of a manufacturer includes a seller who (1) has actual knowledge of a defect in the product; (2) creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant control over all or a portion of the manufacturing process; (3) alters or modifies the product in any significant manner after the product comes into the sellers possession and before it is sold to the ultimate user or consumer; (4) is owned in whole or significant part by the manufacturer; or, owns in whole or significant part the manufacturer. Ind. Code § 34-6-2-77(a).

⁶ A seller is defined as “a person engaged in the business of selling or leasing a product for resale, use, or consumption.” Ind. Code § 34-6-2-136.

by a product, *regardless of the substantive legal theory of theories upon which the action has been brought*. Ind. Code § 34-20-1-1 (emphasis added); *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 976 (Ind. 2002); *Campbell v. Supervalue, Inc.*, 565 F.Supp.2d 969, 976 (N.D. Ind. 2008) (holding that a plaintiff's "attempt to cast [defendant]'s action as one of 'simple negligence,' and therefore somehow falling outside the reach of the Indiana Product Liability Act, clearly fails"); *Cincinnati Ins. Cos v. Hamilton Beach/Proctor-Silex, Inc.*, 2006 U.S. Dist. LEXIS 9807, at *2 (N.D. Ind. Feb. 7, 2006); *Ryan v. Philip Morris USA, Inc.*, 2006 U.S. Dist. LEXIS 9077, at *9 (N.D. Ind. Feb. 22, 2006); *Conley v. Lift-All Co.*, 2005 U.S. Dist. LEXIS 15468, 12-13 (S.D. Ind. July 25, 2005) ("[t]he IPLA effectively supplants [] common law claims because all [] claims are brought by a user or consumer against a manufacturer for physical harm caused by a product. Plaintiff's common law claims will therefore be treated as merged into the IPLA claims.").

Plaintiff's Complaint predicates her manufacturing defect and failure to warn claims under theories of strict liability, negligence, negligence *per se*, breach of express and implied warranties, misrepresentation, alter-ego liability, and joint venture liability. Even putting aside the conclusory assertions in the Complaint, Plaintiff's common law claims of negligence and negligence *per se* (Counts II and III) are pre-empted or subsumed by the IPLA as a matter of law. See *American Intern. Ins. Co. v. Gastite*, 2009 WL 1383277, *2 (S.D. Ind. 2009); *Ganahl v. Stryker Corp.*, No. 1:10-cv-1518-JMS-TAB, 2011 WL 693331, at *3 (S.D. Ind. Feb. 15, 2011) (plaintiff's common law negligence and strict product liability claims arising out of personal injuries suffered from use of medical device were subsumed by IPLA).

Plaintiff's claims for breach of express and implied warranties (Count V) are also subsumed by the IPLA. "The Indiana Court of Appeals and several federal district courts sitting

in Indiana have all held that tort-based breach of warranty claims have been subsumed into the [I]PLA." *Hathaway v. Cintas Corporate Services*, No. 1:10 CV 195, 2012 WL 4857828, at *2 (N.D. Ind. Oct. 11, 2012) (Moody, J.).⁷ Because Plaintiff's claims for breach of express and implied warranties are all based in tort, the IPLA provides the exclusive remedy, thereby barring any common law cause of action for breach of warranty. *Id.*, at *3 (holding that plaintiff's common law claims for breach of express and implied warranties arising out of severe burn injuries from spark created by machine used to cut metal were subsumed under IPLA); *Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011) (express warranty claim based in tort supplanted by IPLA).

Plaintiff's breach of implied and express warranty claims are further pre-empted by the IPLA because the claims are based in tort and she has not sought recovery for damage to the product itself or any economic loss arising from the failure of the product to work as expected. See *Hathaway, supra*, 2012 WL 4857828 at *2, citing *Gunkel v. Renovations, Inc.*, 822 N.E.2d 150, 153 (Ind. 2005) ("Indiana law under the Products Liability Act and under general negligence law is that damage from a defective product or service may be recoverable under a tort theory if the defect causes personal injury or damage to other property, but contract law governs damage to the product or service itself and purely economic loss arising from the failure of the product or service to perform as expected").

Plaintiff's common law misrepresentation claim (Count IV) is also subsumed by the IPLA. Plaintiff asserts that the Defendants concealed or falsely stated information pertaining to the contaminant free status of MAP in connection with the marketing, sale, and distribution of

⁷ See also *Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011); *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc.*, No. 4:05 CV 49, 2006 WL 299064, at *3 (N.D. Ind. Feb. 7, 2006); *N.H. Ins. Co. v. Farmer Boy AG, Inc.*, No. IP 98-0031-C-T/G, 2000 WL 33125128, at *3 (S.D. Ind. Dec. 19, 2000); and, *Condon v. Carl J. Reinke & Sons, Inc.*, 575 N.E.2d 17, 18 (Ind.Ct.App.1991).

the compound from the Plaintiff, Plaintiff's physician, medical provider, medical facility, and State and Federal regulatory agencies. *See Pl. Comp.*, ¶ 34. Ostensibly, Plaintiff claims that she suffered personal injuries from a contaminated MAP injection as a result of her reliance on the alleged misrepresentations that the injections were safe. Plaintiff's misrepresentation claim, like the breach of warranty claims, is based in tort for physical injuries allegedly caused by a product that was manufactured or sold by the Defendants. Accordingly, the misrepresentation claim is supplanted by the IPLA. *See Ryan v. Philip Morris USA, Inc.*, No. 1:05CV162, 2006 WL 449207 (N.D. Ind. 2006) (ruling that *all of plaintiff's claims, including her negligence and fraud claims, fall within purview of IPLA*) (emphasis added); *McGookin v. Guidant Corp.*, 942 N.E.2d 831 (Ind. Ct. App. 2011) (observing that trial court correctly merged all claims, including claims for actual and constructive fraud, into a single cause of action under the IPLA).

Due to the failure of the above-referenced Counts, Plaintiff's punitive damage claim (Count VIII) similarly fails. A request for punitive damages must be supported by "at least" a general factual allegation consistent with the applicable state-law elements for an award of punitive damages. *Gorman v. Saf-T-Mate, Inc.*, 513 F.Supp. 1028, 1037 (N.D. Ind. 1981). Plaintiffs' Complaint asserts *no* factual allegations against Alaunus to support a claim for punitive damages. Count VIII of Plaintiffs' Complaint does not even mention Alaunus. Moreover, Indiana does not recognize a separate and distinct cause of action for punitive damages. *See Baker v. Westinghouse Elec. Corp.*, 830 F.Supp. 1161, 1167 (S.D. Ind. 1993) *citing Grimes v. Jones*, 567 N.E.2d 858, 860 (Ind. Ct. App. 1991). Accordingly, Plaintiffs' punitive damage claim (Count VIII) must be dismissed.

Indiana's IPLA, as well as the case law interpreting the Act, clearly instruct that claims involving allegedly defective products are exclusively governed by the IPLA, thereby precluding

all other tort claims. Accordingly, Counts I – VI of Plaintiff's Complaint asserting common law claims are subsumed by the IPLA and must be dismissed. Additionally, because Plaintiff has failed to assert a claim under the IPLA, each common law claim is subject to dismissal. *See Kirksey v. R.J. Reynolds Tobacco Co.*, 168 F.3d 1039, 1042 (7th Cir. 1999) ("a claim that does not fit into an existing legal category requires more argument by the plaintiff to stave off dismissal, not less, if the defendant moves to dismiss on the ground that the plaintiff's claim has no basis in law").

C. Plaintiff's Complaint Fails to State a Claim Under the IPLA

Even if this Court were to indulge the Plaintiff by treating the Complaint as if it plead a claim under the IPLA – which it does not – the Complaint nevertheless fails to state a viable claim for relief under the IPLA. When Indiana Code sections 34-20-1-1 and 34-20-2-1 are read together, there are five (5) unmistakable threshold requirements for IPLA liability: (i) a claimant who is a user or consumer and is also in the class of persons that the seller should reasonably foresee as being subject to the harm caused; (ii) a defendant that is a manufacturer or a seller engaged in the business of selling a product; (iii) physical harm caused by a product; (iv) a product that is in a defective condition unreasonably dangerous to a user or consumer or to his property; and (v) a product that reached the user or consumer without substantial alteration in its condition. *See Ind. Code 34-20-1-1; 34-20-1-2. Bourne v. Marty Gilman, Inc.*, 452 F.3d 632, 635 (7th Cir.2006); *Williams v. REP Corp.*, 302 F.3d 660 (7th Cir. 2002); “[A] plaintiff can satisfy the second element—that the product was defective—by showing one of the following: a design defect, a manufacturing defect, or a failure to warn.” *Ritchie v. Glidden Co.*, 242 F.3d 713, 720 (7th Cir.2001); *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 161 (Ind.Ct.App.1997). Plaintiff's Complaint falls short of satisfying any of these elements.

First, the Complaint does not sufficiently allege that the Plaintiff was a "user or consumer" of a product that was manufactured or sold by Alaunus. While the Complaint alleges that the Plaintiff "received one or more of these epidural steroid injections . . . of an injectable steroid," it does not plead any specifics regarding the name of the drug or compound that the Plaintiff was allegedly treated with; the name of the manufacturer listed on the labeling of the product; the lot number or product code of any product used or consumed; whether the product was brand name or generic; the type and strength of the drug or compound; or whether the product was preservative free or not. In the absence of such facts, the Complaint does not give rise to a reasonable inference that Plaintiff used or consumed any product whatsoever, let alone a product manufactured or sold by Alaunus. *See Iqbal*, 129 S.Ct. at 1950, *citing Twombly*, 127 S.Ct. 1955. Consequently, even an assumed IPLA claim against Alaunus must be dismissed because the Complaint fails to plead facts showing that Plaintiff is a "user" or "consumer" within the meaning of the IPLA.

Second, the Complaint does not sufficiently allege that Defendant Alaunus is a "manufacturer" or a "seller" engaged in the business of selling MAP. As set forth above, the only allegations in the Complaint that even mention Alaunus are contained in Count VI (Alter-Ego, Joint Venture) and those allegations are so conclusory that they are not entitled to be taken as true on a 12(b)(6) motion. Thus, there are no factual allegations in the Complaint *showing*⁸ that Alaunus designed, assembled, fabricated, produced, constructed, or otherwise prepared MAP or any of its components prior to its sale. Because the Plaintiff has failed to show that Alaunus is a "manufacturer" or "seller," the Complaint does not state a plausible manufacturing

⁸ Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint should be dismissed because it has alleged – but it has not “shown” – “that the pleader is entitled to relief.” *Iqbail*, 129 S.Ct. at 1950.

defect or failure to warn claim under the IPLA.⁹ See *Williams v. REP Corp.*, 302 F.3d 660, 666 (7th Cir. 2002) (defendant that did not sell, lease or otherwise put into the stream of commerce the machine that caused plaintiff's injury could not be held liable under the IPLA); *Chappay v. Ineos USA L.L.C.*, No. 2:08-CV-271, 2009 U.S. Dist. LEXIS 24807 (N.D. Ind. Mar. 23, 2009) (dismissing PLA claim concluding that the plaintiff had "not alleged that [defendant] was a manufacturer or a seller of any product" and that she likewise had "failed to specifically identify a product").¹⁰

Third, Plaintiff's Complaint does not sufficiently allege that the injection that Plaintiff purportedly received suffered from a manufacturing defect (i.e., fungal contamination). Notably, the only specifically alleged injury in the Complaint is contraction of meningitis from the steroid

⁹ In paragraph 26 of the Complaint, Plaintiff includes a laundry-list of defect claims including a breach of a pre-sale and post-sale duty to warn. To the extent that Plaintiff claims that Alaunus breached a pre-sale duty to warn the Plaintiff of potential serious adverse reactions associated with the use of **non-contaminated** MAP, any such claim fails under the learned intermediary doctrine. See *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548-49 (Ind. Ct. App. 1979) (since drugs are available only by prescription, a manufacturer's duty to warn extends only to the medical profession, and not the ultimate users); *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 303 (7th Cir. 1987) (manufacturer of catheter had no duty to warn users of the catheter other than the operating surgeon who installed the catheter); *Menges v. DePuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999). See also *Peters v. Judd Drugs, Inc.*, 602 N.E.2d 162 (Ind. Ct. App. 1992) (pharmacy that had no direct contact with patient had no duty to warn patient of adverse drug effects); *Hook's SuperX, Inc. v. McLaughlin*, 642 N.E.2d 514 (Ind. 1994) (duty to warn patients of adverse effects of drugs generally lies with physician, not pharmacist); *Allberry v. Parkmore Drug, Inc.*, 20A03-0503-CV-125, (Ind. Ct. App. Sept. 16, 2005) (finding no pharmacist duty to warn patient of side effects nor a pharmacist duty to give patient the manufacturer's product information, containing warnings, that wasn't included in prescription itself).

¹⁰ See also *Patterson v. Novartis Pharmaceuticals Corp.*, 451 Fed. Appx. 495 (6th Cir. Aug. 23, 2011) (affirming dismissal for failure to state a claim because Massachusetts law requires that a plaintiff suing a manufacturer in a product-liability action be able to prove that his or her injury can be traced to that specific manufacturer and the factual allegations in the complaint only permitted the Court to infer the possibility that the plaintiff received infusions of the name-brand drug, Aredia, manufactured by Novartis, as opposed to the generic equivalent manufactured by some other manufacturer); *In re Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. April 9, 2010) (dismissing all product liability claims on grounds that plaintiff's complaint failed to allege sufficient facts to identify manufacturer of product observing that statement in the complaint that "Defendants, either directly or through [their] agents, apparent agents, servants, or employees, at all relevant times, designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax and Boniva" was conclusory since the complaint did not provide any specifics to support such a conclusion); *Johnson v. Moog, Inc.*, 2011 WL 719600 (E.D. Tex. Feb. 22, 2011) (all claims in medical device case dismissed under *Twombly-Iqbal* because the pleading asserted only that unknown "defendants" committed actions and failed to state sufficient facts to identify defective product).

injection product. According to the FDA-approved labeling,¹¹ meningitis (when administered under the arachnoid membrane of the brain or the spinal cord) and other adverse reactions and side effects of headaches, chest/neck/back pain, flu-like symptoms, and neurological issues, are all associated with clinical use of ***non-contaminated brand-named*** injectable methylprednisolone acetate.¹² While the Complaint alleges that “contaminated” MAP was distributed into interstate commerce, *Pl. Comp.* at ¶ 7, the Complaint does not allege any specifics regarding the alleged contaminated injection, such as the lot numbers of the injection vials that were distributed to the Plaintiff’s medical provider, OSMC; the lot number or product code of the injection vial allegedly used to treat the Plaintiff; the name of the manufacturer listed on the injection vial that was used to treat the Plaintiff; the volume of the injection vial; or whether the Plaintiff received an injection of preservative free formula or not. Moreover, the FDA-approved labeling of the ***brand-named*** version of methylprednisolone acetate states that meningitis is a serious adverse reaction associated with ***non-contaminated*** product; therefore it is insufficient to suggest that the steroid injection Plaintiff purportedly received was contaminated simply because she alleges that she contracted meningitis. *See Smith v. Michigan Beverage Co.*, 495 F.2d 754, 757 (7th Cir. 1974) (“Just as it is the general rule that the mere fact

¹¹ This Court may consider the contents of the FDA-approved labeling for methylprednisolone acetate on a motion to dismiss under Rule 12(b)(6) without converting the motion to one for summary judgment because it is an official public record susceptible to judicial notice under Federal Rule of Evidence 201 and/or a document central to the Plaintiff claim. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1998); *City of Sausalito v. O’Neill*, 386 F.3d 1186, 1223 n.2 (9th Cir. 2004) (“We may take judicial notice of a record of a state agency not subject to reasonable dispute”); *O’Toole v. Northrop Grumman Corp.*, 499 F.3d 1218, 1225 (10th Cir. 2007) (“It is not uncommon for courts to take judicial notice of factual information found on the world wide web”); *New Mexico ex rel. Richardson v. Bureau of Land Management*, 563 F.3d 683 (10th Cir. April 28, 2009) (No. 06-2352, 06-2353, 06-2354) (taking judicial notice of releases which were referred to on the websites of two federal agencies because it was not subject to reasonable factual dispute and is capable of determination using sources whose accuracy cannot reasonably be questioned).

¹² See U.S. FDA, MedWatch: The FDA Safety Information and Adverse Event Reporting Program, Safety Information – Depo-Medrol/S-085 Label (brand named methylprednisolone acetate injectable suspension, USP), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/011757s085s086lbl.pdf (accessed Jan. 3, 2013).

of injury will not create an inference of negligence, the mere fact of the accident cannot create an inference of a defect in a products case") (applying Indiana law); *Gaskin v. Sharp Electronics Corp.*, 2007 WL 2819660, *5 (N.D. Ind. Sept. 26, 2007) ("the mere fact that an accident occurred does not create an inference of a defect in a products liability case").

Plaintiff's Complaint also does not plead sufficient facts to identify Alaunus as the manufacturer of the allegedly defective MAP injection. Given that the Complaint does not establish *any* connection between the allegedly contaminated product and the product the Plaintiff supposedly received from her physician, the Complaint does not give rise to a reasonable inference that the Plaintiff received an injection of contaminated product from Alaunus or that Alaunus is liable for the alleged misconduct. *See Iqball*, 129 S.Ct. at 1950 (where the well pleaded facts do not permit the court to infer more than a mere possibility of misconduct the complaint should be dismissed because it has alleged but not shown that the pleader is entitled to relief.)

In sum, Plaintiff has woefully failed to plead sufficient facts to give rise to a reasonable inference that Alaunus may be held liable under the IPLA. Consequently, Counts I – VIII of Plaintiff's Complaint should be dismissed for failure to state a claim pursuant to Fed.R.Civ.P. 12(b)(6). Plaintiff's Complaint is subject to dismissal based on the IPLA alone; however, even without the IPLA, Plaintiff's Complaint fails for additional reasons discussed below.

D. Plaintiff's Negligence Per Se Claim (Count III) Also Fails Because There is No Private Right of Action Under the Food Drug and Cosmetic Act

Even if this Court were to find that Plaintiff's negligence *per se* claim (Count III) is not subsumed by the IPLA (which it is), the claim nevertheless fails for two (2) reasons. First, the negligence *per se* claim fails as a matter of law because it is based upon violations of the Federal Food Drug & Cosmetic Act ("FDCA") (codified at 21 U.S.C. s. 301, *et. seq.*) and there is no

private right of action under that statute. *See Martin v. Ortho Pharmaceutical Corp.*, 661 N.E.2d 352, 355-56 (Ill. 1996) (regulations under FDCA could not form the basis of negligence *per se* claim because Congress did not intend for a private right of action under the FDCA).¹³ Second, the negligence *per se* claim should be dismissed for failure to plead a plausible claim under the *Twombly-Iqbal* standard because Rhodes's claim is based upon unspecified violations of a federal statute and other unspecified violations of federal and state regulations. *See Chappay v. Ineos USA L.L.C.*, No. 2:08-CV-271, 2009 U.S. Dist. LEXIS 24807 (N.D. Ind. Mar. 23, 2009) (dismissing plaintiff's negligence *per se* claim under *Twombly* because complaint failed to identify a specific statute, regulation, or ordinance to support her claim of negligence *per se*).¹⁴

While Indiana courts have recognized negligence for statutory violations, *see Kho v. Pennington*, 875 N.E.2d 208, 212 (Ind. 2007), the unexcused violation of a statutory duty constitutes negligence *per se* "if the statute or ordinance is intended to protect the class of persons in which the plaintiff is included and to protect against the risk of the type of harm which has occurred as a result of its violation." *Id.* at 212-13 (citation omitted). "When a civil tort action is premised upon violation of a duty imposed by statute, the initial question to be

¹³ See also *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 789-90 (3d Cir. 1999) (affirming dismissal of negligence *per se* claim because "plaintiffs did not invoke the statutory violations under the FDCA to prove the defendants' liability for a separate underlying tort, but instead contend the violations themselves form a cause of action. This interpretation of *per se* liability would allow private plaintiffs to recover for violations of a federal statute that creates no private cause of action and, in fact, expressly restricts its enforcement to the federal government. Plaintiff's theory would undermine section 337(a) by establishing a private, state-law cause of action for violations of the FDCA"); *In re Shigellosis Litigation*, 647 N.W.2d 1, 10 (Minn. App. 2002); *Bish v. Smith & Nephew Richards, Inc.*, 2000 WL 1294324, at *3 (Tenn. App. Aug. 23, 2000); *Osburn v. Danek Medical, Inc.*, 520 S.E.2d 88, 93 (N.C. App. 1999), aff'd, 542 S.E.2d 215 (N.C. 2000).

¹⁴ See also *Ilarraza v. Medtronic, Inc.*, 677 F.Supp.2d 582 (E.D.N.Y. 2009) ("where, as here, the plaintiff has done nothing more than recite unsupported violations of general regulations [under 21 C.F.R. s. 820, *et seq.*], and fails to tie such allegations to the injuries alleged, the complaint is properly dismissed"); *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1301 (D.Colo.2008) (granting 12(b)(6) motion to dismiss, stating that plaintiff must do more than "allege generally" that the manufacturer did not follow regulations under FDCA and therefore caused the plaintiff's injuries).

determined by the court is whether the statute in question confers a private right of action." *Right Reason Publ'ns v. Silva*, 691 N.E.2d 1347, 1352 (Ind. Ct. App. 1998); *Dawson by Dawson v. Long*, 546 N.E.2d 1265, 1268 (Ind. Ct. App. 1989).

The FDCA does not confer a private right of action to any person. A proceeding to enforce the FDCA or to restrain a violation must be commenced by and in the name of the United States.¹⁵ 21 U.S.C. § 337(a) & (b). It is well-settled that Section 337(a) of the FDCA precludes a private right of action to enforce the statute because the provision states that an action to enforce the statute must be by and in the name of the United States. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352 (2001) (Section 337(a) is "clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government"); *Pacific Trading Co. v. Wilson and Co.*, 547 F.2d 367, 370-71 (7th Cir. 1976) (since FDCA does not provide a cause of action for private parties suing for civil damages, those allegations relating to the statute must be dismissed).¹⁶

E. Plaintiff's Breach of Warranty Claim (Count V) Should Also be Dismissed for Failure to State a Claim Due to Lack of Privity, Failure to Allege a Specific Affirmation of Fact, and Lack of Causation

Similarly, even if Plaintiff's breach of warranty claims (Count V) were not subsumed by the IPLA – which they are – these claims still fail because Plaintiff has not pled facts showing the existence of vertical privity and causation. Under Indiana law, vertical privity is required for claims of breach of express warranty and breach of implied warranty of fitness for a particular purpose. *Davidson v. John Deere & Co.*, 644 F. Supp. 707, 713 (N.D. Ind. 1986) (finding that

¹⁵ A state may commence a proceeding for the civil enforcement of, or to restrain a violation of, certain provisions after giving notice to the federal government.

¹⁶ See also *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 19 n. 4 (1st Cir.1994); *Rodriguez v. SK & F, Co.*, 833 F.2d 8, 9 (1st Cir.1987) (per curiam); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.1994); *Clairol v. Suburban Cosmetics and Beauty Supply, Inc.*, 278 F.Supp. 859, 860-61 (N.D.Ill.1968).

the plaintiff did not have a claim for breach of express warranty because “[p]rivity has not been abrogated as a requirement in contract actions for breach of warranty”); *Hunt v. Unknown Chem. Mfr. No. One*, No. IP 02-389-C, 2003 U.S. Dist. 20138, at *34-35 (S.D. Ind. Nov. 5, 2003) (stating that “a plaintiff bringing a breach of implied warranty of fitness for a particular purpose claim under IND. CODE § 26-1-2-315 must show privity of contract”). “Simply put, vertical privity exists only between immediate links in a distribution chain. A buyer in the same chain who did not purchase directly from a seller is ‘remote’ as to that seller.” *Hyundai Motor Am., Inc. v. Goodin*, 822 N.E.2d 947, 952 (Ind. 2005). Vertical privity “typically becomes an issue when a purchaser files a breach of warranty action against a vendor in the purchaser’s distribution chain who is not the purchaser’s immediate seller.” *Id.* Given that the Complaint does not plead facts showing that Alaunus directly sold the MAP injection to Plaintiff, the claims for breach of express warranty and implied warranty of fitness for a particular purpose claim fail for lack of privity. *See Goodin*, 822 N.E.2d at 952 (express warranty failed for lack of privity); *Davidson*, 644 F. Supp. at 713 (same); *Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011) (claim for breach of implied warranty of fitness for particular purpose dismissed because plaintiff did not state from whom she bought the product or that she entered into any type of bargain or purchase agreement with defendant).

Moreover, in order to recover for breach of an express warranty under Section 2-313 of the UCC, the Plaintiff must show an affirmation of fact or promise made by the seller to the buyer. Plaintiff’s Complaint baldly asserts that that the “Defendants, NECC, Caddens, and Conigliaro” expressly warranted that the MAP injections “were of merchantable quality, safe, and fit for the purpose of their intended use.” *See Pl. Comp.*, ¶ 41. However, the Complaint does not plead any facts, as opposed to conclusory assertions, regarding the specific affirmation

of fact or promise purportedly made by Alaunus to the Plaintiff. The Complaint also fails to identify any of the specific advertisements or promotional materials which were supposedly sent by Alaunus to the Plaintiff. Accordingly, Plaintiff's express warranty claim (Count V) should be dismissed for failure to state a claim pursuant to *Twombly* and *Iqbal*. *See also Heisner v. Genzyme Corp.*, 2008 WL 2940811 (N.D. Ill. July 25, 2008) (express warranty claim in medical device case dismissed under *Twombly* due to plaintiff's failure to specify the language that constituted the warranty since complaint did not allege any particular affirmation, promise, description, or sample that formed part of the basis of his bargain with defendant).¹⁷

Plaintiff's breach of warranty claims also fail due to lack of causation. As set forth above, the Complaint does not plead sufficient facts to show that the Plaintiff's steroid injection was defective. Nor does it show that the Plaintiff suffered an injury as a result of a breach of express or implied warranty by Alaunus. The failure to plead facts showing causation is fatal to all of Plaintiff's express and implied warranty claims. *See Frantz v. Cantrell*, 711 N.E.2d 856, 859 (Ind. Ct. App. 1999) (an action based on breach of warranty requires evidence showing not only the existence of the warranty but also that the warranty was broken and that the breach was the proximate cause of the loss).¹⁸

¹⁷ *See also Johnson v. Brown & Williamson Tobacco Corp.*, 122 F. Supp. 2d 194, 206 (D. Mass. 2000) (dismissing express warranty claim for failure to sufficiently plead facts showing the existence of an express warranty where plaintiff claimed that the defendant extended an express warranty to the Plaintiff through its "advertising, marketing and other efforts," but offered no specific affirmation of fact or promise, nor any particular description, sample or model that might give rise to such a warranty). *Varney v. R.J. Reynolds Tobacco Co.*, 118 F.Supp.2d 63, 70 (D.Mass.2000) (dismissal of express warranty claim appropriate where plaintiff at no point pleads "the existence of anything remotely resembling an express warranty"); *Simmons v. Stryker Corp.*, (D. N.J. 2008) (express warranty claim dismissed under *Twombly* due to plaintiff's failure to specify the language that constituted the warranty and the source material containing the alleged warranty).

¹⁸ *See also Pennsylvania Employees Benefit Trust Fund v. AstraZeneca Pharmaceuticals LP*, 2009 WL 2231686 (M.D. Fla. July 20, 2009) (express warranty claims dismissed under *Twombly-Iqbal* due to failure, in relevant part, to plead any facts in drug case showing proximate cause between breach of warranty and Plaintiff alleged injuries); *Mitchell v. Proctor & Gamble*, 2010 WL 728222 (S.D. Ohio March 1, 2010) (all product liability claims in drug case dismissed under *Twombly-Iqbal* due to failure to plead causation).

F. Plaintiff's Misrepresentation Claim (Count IV) Should Also be Dismissed Because Plaintiff Has Not Plead Facts Sufficient to Create a Reasonable Inference of Liability Against Alaunus

In addition to being supplanted by the IPLA, Plaintiff's misrepresentation claim (Count IV) also fails to state a claim for relief because Indiana does not recognize the type of misrepresentation claim asserted. Even if the claim were recognized, Plaintiff's Complaint fails to plead sufficient facts to make out a plausible claim of negligent misrepresentation resulting in physical injury.

Count IV of Plaintiff's Complaint asserts that the "Defendants, NECC, Caddens and Conigliaro in the marketing/distribution and sale of the aforementioned medications, *negligently* withheld and/or misrepresented to plaintiff, Plaintiff's physician, medical provider, medical facility, other care givers, and State and Federal regulatory agencies, information pertaining to the contaminant free status of said medications." *See Pl. Comp., ¶ 34* (emphasis supplied). Plaintiff is, in essence, asserting a claim of negligent misrepresentation resulting in physical injury of the type described in Section 311 of the Restatement Second of Torts.¹⁹ Significantly, the Indiana Supreme Court in *Passmore v. Multi-Mgmt. Servs. Inc.* refused to adopt Section 311 of the Restatement. 810 N.E.2d 1022, 1025 (Ind. 2004) (where nursing home hired worker in part on basis of favorable recommendation from former employer, worker assaulted a patient, and patient asserted that the former employer wrongly gave a favorable recommendation and should therefore be liable for the injury to the patient, Court held that former employer could be held liable for intentional misrepresentation but not negligent misrepresentation causing physical harm refusing to adopt Section 311 of the Restatement Second of Torts). Count IV of Plaintiff's

¹⁹ Rest. 2nd Torts, § 311 provides: "(1) one who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results (a) to the other, or (b) to such third persons as the actor should expect to be put in peril by the action taken."

Complaint should therefore be dismissed because Indiana does not recognize negligent misrepresentation claims resulting in physical injury, as opposed to pecuniary harm.

Even if this Court did recognize a claim for negligent misrepresentation resulting in physical injury, the claim should further be dismissed because it does not comport with Rule 8(a). The Complaint does not plead any facts indicating that there were any communications whatsoever – direct or indirect – between Alaunus and the Plaintiff, or specifying what false information, if any, was provided by Alaunus to the Plaintiff. The audience or recipient of the false statement must be the Plaintiff, not the Plaintiff's physician or the "general public." *See, e.g., In re Guidant*, 2008 U.S. Dist. LEXIS 24797, at *16 (quoting *U.S. ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.2d 601, 605 (7th Cir. 2005) (noting the requirement that the misrepresentation be communicated to the plaintiff)).

The Complaint does not allege any direct communication between the Plaintiff and any of the Defendants, let alone, Alaunus. The Complaint also does not plead any facts concerning the manner in which Rhodes allegedly relied on any information provided by Alaunus or how such reliance caused Plaintiff's injury. Because the assertion that Alaunus negligently misrepresented information concerning MAP to the Plaintiff is without any factual support, the Complaint does not state a plausible claim for misrepresentation and should therefore be dismissed under *Twombly-Iqbal* pursuant to Rule 12(b)(6).

G. Plaintiff's Alter-Ego, Joint Venture Claim (Count VI) Should Also be Dismissed Because Plaintiff Has Not Plead Facts Sufficient to Create a Reasonable Inference of Liability Against Alaunus

As discussed above, Count VI of Plaintiff's Complaint is also subsumed by the IPLA and must be dismissed. However, even if Count VI were not subsumed by the IPLA, the claim still fails because Plaintiff has asserted nothing more than conclusory allegations, not facts, which are

insufficient to create a reasonable inference of liability.

In determining whether a corporation is merely an alter-ego of another corporation, the courts consider whether (1) similar corporate names were used; (2) the corporations shared common principal corporate officers, directors, and employees; (3) the business purposes of the corporations were similar; (4) the corporations were located in the same offices and used the same telephone numbers and business cards; (5) there was intermingling of business transactions, functions, property, employees, funds, records, and corporate names in dealing with the public. *See Ziese & Sons Excavating, Inc. v. Boyer Constr. Corp.*, 965 N.E.2d 713, 719 (Ind. Ct. App. 2012). For a joint venture to exist, the parties must be bound by an express or implied contract providing for (1) a community of interests, and (2) joint or mutual control, that is, an equal right to direct and govern the undertaking, that binds the parties to such an agreement. *Byrd v. E.B.B. Farms*, 796 N.E.2d 747, 753 (Ind. Ct. App. 2003), *trans. denied* (*citing Inland Steel v. Pequignot*, 608 N.E.2d 1378, 1382 (Ind. Ct. App. 1993)).

Here, there are absolutely no factual allegations, as opposed to conclusory assertions, in the Complaint showing the presence of any of the factors considered by the courts in determining whether an entity is liable under an alter-ego or joint venture theory. Thus, paragraphs 50 - 52, and 57 of the Complaint, which recite the alter-ego and joint venture theories, fail under *Twombly-Iqbal* because they are merely a formulaic recitation of the causes of action and nothing more; they do not put Alaunus on notice of what exactly it might have done to be liable under an alter-ego or joint venture theory. *See Resolution Trust Corp. v. Driscoll*, 985 F.2d 44, 48 (1st Cir. 1993) (affirming dismissal of claims against corporate defendant because naked assertion of alter ego liability was not supported by sufficient factual allegations); *De Jesus v. Sears, Roebuck & Co.*, 87 F.3d 65, 70 (2d Cir. 1996) (granting 12(b)(6) motion to dismiss since

complaint was “devoid of any specific facts or circumstances supporting” liability of an individual on a veil piercing theory); *Fojtasek v. NCL (Bahamas) Ltd.*, 613 F.Supp.2d 1351 (2009) (S.D. Fla. May 11, 2009) (dismissing joint venture claim where plaintiff’s complaint merely alleged in conclusory fashion that defendants were engaged in a joint venture).²⁰

H. Plaintiff’s Claims Against Alaunus Should Also be Dismissed Because Plaintiff Impermissibly “Lumps” the Allegations Such That The Allegations Are Indistinguishable As Between the Defendants

Finally, Plaintiff’s Complaint is also subject to dismissal because the Complaint impermissibly “lumps” all Defendants together as one, such that it is impossible to distinguish what conduct is alleged against which Defendant. Per Rule 12(b)(6), a complaint is subject to dismissal where the complaint fails to provide an adequate factual basis to distinguish the conduct of particular defendants. *Goren v. New Vision Intern., Inc.*, 156 F.3d 721, 730 (7th Cir. 1998) (affirming dismissal of complaint where complaint treated defendants as one, “lumping” them together); *Bagheri v. Galligan*, 160 Fed. Appx. 4, 5 (1st Cir. 2005) (upholding district court’s dismissal of action where the original complaint did not “state clearly which defendant or defendants committed each of the alleged wrongful acts.

“By lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [plaintiff]’s complaint failed to satisfy [the] minimum standard of pleading under Fed.R.Civ.P. 8(a).” *Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2d Cir. 2001). *See also Vanzandt v. OK Dep’t Human Serv’s.*, 276 Fed. Appx. 843 (10th Cir. 2008)

²⁰ *Lovely Peoples Fashion, Inc. v. Magna Fabrics, Inc.*, 95 CIV. 8450 AGS, 1996 WL 732634, *5 (S.D.N.Y. Dec. 19, 1996) (granting motion to dismiss against individual shareholders for failure to “state some basis in fact for piercing the corporate veil” where complaint’s sole allegation was that shareholders “control and operate the [corporation] as their alter egos for the benefit of themselves and their families”); *Centrifugal Air Pumps Australia v. TCS Obsolete, LLC*, 610-CV-820-ORL-31DAB, 2010 WL 3584948 at *2 (M.D. Fla. Sept. 9, 2010) (plaintiff’s failure to plead facts in support of its conclusory veil piercing allegations required dismissal of individual LLC members from action).

(“To carry their burden, plaintiffs under the *Twombly* standard must do more than generally use the collective term ‘defendants’ . . . This is because the purposes of plausibility, notice, and gate keeping are best served by requiring plaintiffs to directly link an actual individual with the alleged improper conduct”).

Here, Plaintiff’s Complaint impermissibly “lumps” Defendants NECC, the Caddens, Conigliaro and Alaunus together because it merely refers to them collectively as “Defendants” or “Defendants, NECC” and fails to plead any basis to distinguish the conduct of Alaunus from that of NECC and the individually named Defendants. Plaintiff’s Complaint should be dismissed pursuant to *Twombly-Iqbal* because the allegations in the pleading fail to give adequate notice to Alaunus as to what it did wrong and therefore fails to meet the pleading standards of Rule 8. *See Goren*, 156 F.3d at 730; *Bagheri*, 160 Fed. Appx. at 5 (1st Cir. 2005); *Atuahene*, 10 Fed. Appx. at 34 (2d Cir. 2001); *Vanzandt*, 276 Fed. Appx. at 843.²¹

V. CONCLUSION

Plaintiff’s Complaint must be dismissed for failure to state a claim pursuant to Rule 12(b)(6). Plaintiff’s Complaint fails under the *Twombly-Iqball* standard to assert sufficient factual allegations beyond non-conclusory formulaic recitations of various causes of action. In addition, Counts I – VI of Plaintiff’s Complaint are pre-empted by the IPLA – the exclusive remedy for personal injury claims involving allegedly defective products. Even if Plaintiff’s claims were not pre-empted by the IPLA – which they are – Plaintiff’s Complaint fails to plead facts sufficient to create an reasonable inference of liability against Alaunus. For these reasons,

²¹ See also *Jackson v. Federal Bureau of Investigation*, 2007 WL 433143, at *3 (N.D. Ill. Jan. 31, 2007) (dismissing complaint under Rule 8 because it “fails to properly identify which of the multiple defendants engaged in the alleged conduct”); *Nagel v. ADM Investor Serv.’s, Inc.*, 995 F. Supp. 837, 845 (N.D. Ill. 1998) (dismissing complaint under Rule 8 because it fails to properly identify which of the multiple defendants engaged in the alleged conduct).

Plaintiff is not entitled to conduct any discovery to cure the defects in her pleading.²² Plaintiff's Complaint must be dismissed in its entirety, or at the very least as to Alaunus, pursuant to Fed.R.Civ.P. 12(b)(6).

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on February 6, 2013 using the CM/ECF system which sent notification of this filing to the following:

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²² See *Twombly*, 127 S. Ct. at 1966 (rejecting arguments that a plaintiff should be permitted to proceed with discovery and that case management techniques may be used by defendants to weed out baseless claims in an anti-trust case ruling that one of the main goals of the plausibility standard is the avoidance of unnecessary discovery and discovery would be massive since the Plaintiff represents a putative class of at least 90 percent of all subscribers to local telephone or high-speed Internet service in the continental United States in an action against America's largest telecommunications firms, Supreme Court); *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005) ("something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with `a largely groundless claim' be allowed to `take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value'").